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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,980

03/31/2004

Edward Wells Knowlton

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25213 7590 10/12/2007  
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EXAMINER
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SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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10/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/813,980

Applicant(s)

KNOWLTON, EDWARD WELLS

Examiner

Thomas J. Sweet

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments, see page 8 of the remarks, filed 09/18/2007, with respect to the rejection under 35 USC 112 have been fully considered and are persuasive. The rejection of claims 2, 3 and 14 under 35 USC 112 has been withdrawn.

Applicant's arguments filed 09/18/2007 have been fully considered but they are not persuasive. The amendment to claims 1 and 30 is not a positive recitation of limitation, the language "can be used" is an alternative render the limitation indefinite (i.e. the limitation need not be met since it is optional). With regard to the Double patenting rejection, the rejection stand as previously rejected since alternative language is used in the amendment. With regard to the rejection under 35 USC 102 and 103, for the reasons previously outline in the office action 03/19/2007 Knowlton does anticipate the claims. The new limitation is not positively recited and therefore is optionally, so the claims remain rejected as in the 03/19/2007 office action. Knowlton clearly include pre-positioning for example in the background of the invention liposuction is use prior to the treatment which constitutes pre-positioning. Additionally, it is inherent to pre-positioning the patient so as to access the treatment area which also constitutes pre-positioning.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

Art Unit: 3774

the invention. Regarding claims 1 and 30 (and the dependent claims), the phrase "can be used" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(h).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 8, 10-22, 24-26 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7 and 17 of U.S. Patent No. 6470216. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 6470216 encompass the steps of the current application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-24, 26-29, 31-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton (US 6,350,276). Knowlton discloses a method of energetically treating a target tissue site (col 11-12, thermal), the method comprising: pre-positioning tissue in a aesthetically (background on the invention, such as line 40-42 and inherent positioning of the patient for access) correct configuration (cols 19-20, lines 62-3, contact and pressure are required otherwise there is no current flow) delivering energy to the tissue site using an energy delivery device (col 12, lines 5-11); delivering a vectored mechanical force to the tissue site (col 12, lines 5-11); producing a thermal adhesion or lesion at the tissue site (i.e. cleave of collagen crosslinks); and remodeling at least a portion of tissue at the tissue site (to achieve a smoother contour).

With regard to claims 2 and 3, inherently a patient is pre-positioned for treatment (e.g. a patient is placed on an operating table, standing, etc...) in conjunction with the treatment.

With regard to claims 22, 33, 37 and 39, selecting the tissue site based on an amount of convexity at the tissue site (inherent to smooth the contour).

With regard to claims 4-7, 31, 35-36 and 38, producing a plurality of adhesions or lesions is substantially continuous or at least partially overlapping and delivering energy in a selected pattern (Col 6, lines 5-48, discontinuous modes/pattern of application, specifically lines 22-23 states power is pulsed which is overlapping and a pattern).

With regard to claim 8, the force is a substantially uniform force applied over the tissue site (col 12, line 17).

With regard to claims 9-10, force profile with respect to a radial direction of a force application surface, the force profile substantially increasing in an inward direction with respect to an edge of the force application surface (col 17, lines 8-22- the tissue interface inherently applies this force profile by having radiused edges and as described in the paragraph from col 18-19)

With regard to claim 11, delivering a first force in a first direction and delivering a second force in a second direction (col 12, lines 17-24).

With regard to claim 14, pre-positioning tissue at the tissue site substantially prior to energy delivery to shape the tissue adhesion or lesion or create a directed wound healing response (the disclosed bipolar RF energy system requires contact with the skin to work and the tensioning device 16 is separate from the electrodes 18 which pre-contact the tissue as the electrode are brought into contact with the tissue).

With regard to claims 15-16, 19, 34 and 38, cooling a layer of tissue or a surface layer of tissue of at least a portion of the tissue site (col 4, lines 7-9) and producing a reverse thermal gradient within at least a portion of the tissue site (col 5, lines 52-59) which preserves at least a portion of a surface, a tissue layer or an epidermal layer at or adjacent the tissue site.

With regard to claims 27 and 29, performing a liposuction procedure substantially at the tissue site (col 1-2, lines 54-16).

With regard to claim 28, skeletonizing at least a portion of fibrous septae at the tissue site (an unintended side effect as discussed in Col 12 lines 34-49).

Art Unit: 3774

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 13, 25 and 30 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Knowlton. Knowlton discloses a method of energetically treating a target tissue site as discussed above including a positive force (positive pressure, greater than zero). Knowlton anticipated and clearly envisaged the range (range of .01-10 ... 2.5-10 lbs) by having a range (greater than zero) overlapping the claimed ranges. It this does not establish sufficient specificity. Applicant has not disclosed that having force in the claimed ranges solves any stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well with any positive force up to the point of tissue destruction. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the range of 2.5-10 lbs because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Knowlton.

### *Conclusion*

This is a RCE of applicant's earlier Application No. 10/813980. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in

this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

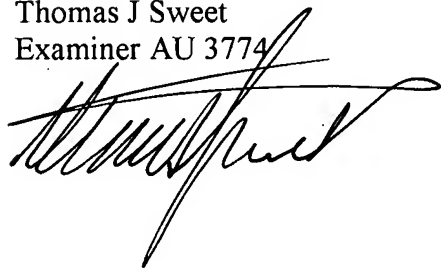


Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet

Examiner AU 3774

A handwritten signature in black ink, appearing to read 'Thomas J Sweet', written over the printed name and title.